510(k): K092793

Bio-Medical Research Ltd.

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This summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

DEC - 7 2009

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Prepared:	20th November 2009

2. Device Name

Trade Name of Device:	Kneehab Conductive Garment
Common Name:	Conductive Garment
Classification Name:	Cutaneous Electrode
Regulation Number:	21 CFR 882.1320
Product Code:	GXY

3. Identification of Equivalent Legally Marketed Device

Name:	Kneehab XP Conductive Garment, Type 411
Manufacturer:	Bio-Medical Research Ltd.
510(k) No:	K083105

Name:	Lumbofix™ Conductive Garment
Manufacturer:	Bio-Medical Research Ltd.
510(k) No:	K091317

4. Description of Device

The proposed Kneehab XP Conductive Garment is an integrated thigh wrap garment designed to be used in conjunction with a Neurotech stimulator and custom electrodes for the application of neuromuscular electrical stimulation (NMES) to the quadriceps muscles of the

thigh. The garment is supplied with a set of four custom designed adhesive pads which may positioned on the inner garment outlines according to fit of the user. Instructions are provided in the user instructions for correct electrode placement. For purposes of hygiene, the garment may be cleaned and instructions for device care are included in the user manual.

5. Statement of Intended Use/Indications for Use

The Neurotech Kneehab XP Conductive Garment and associated accessories are indicated for use with Neurotech stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the quadriceps area of the leg.

6. Technological Characteristics

This submission differs from the the Kneehab XP cleared under K083105 in that it is not packaged with the battery pack, charger or a control unit.

7. Clinical and Non-Clinical Tests

No clinical or non clinical tests were performed to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Bio-Medical Research Ltd.
c/o Ms. Anne-Marie Keenan
Quality/Regulatory Engineer
Parkmore Business Park West
Galway, Ireland

DEC - 7 2009

Re: K092793
Trade/Device Name: Kneehab XP Conductive Garment, Model 411
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated: September 3, 2009
Received: September 11, 2009

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jessica Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092793

Device Name: Kneehab XP Conductive Garment

Indications for Use:

The Neurotech Kneehab Conductive Garment and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the quadriceps area of the leg.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092793